



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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|-------------|----------------|-----------------|------------------------|
| Applicant: | WAGNER et al. | Examiner: | Unassigned |
| Serial No.: | 10/804,476 | Group Art Unit: | 3762 |
| Filed: | March 19, 2004 | Docket No.: | GUID.628PA (03-526) |

Title: ELECTRODE PLACEMENT DETERMINATION FOR SUBCUTANEOUS
CARDIAC MONITORING AND THERAPY

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence and the papers, as described hereinabove, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to:, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on June 30, 2004.

6/30/04

By:

Kelly S. Waltigney

INFORMATION DISCLOSURE STATEMENT (37 C.F.R. §1.97(b))

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Forms 1449 (5 sheets) are brought to the attention of the Examiner.

This statement should be considered because it is submitted either within three months of the filing date or before the first Office Action of the above-identified application. Accordingly, no fee is due for consideration of the items listed on the enclosed Forms 1449.

In accordance with 37 C.F.R. §1.98(a)(2), and the 05 August 2003 Official Gazette Notice, only a copy of each foreign document or non-U.S. patent/application listed on the enclosed Forms 1449 is provided.

Serial No. 10/804,476
Filed: 03/19/2004
Information Disclosure Statement

Please note that any notations or markings on the attached documents do not reflect particular relevance, or lack thereof, to the present application, nor were they necessarily made by anyone affiliated with the prosecution of the present application.

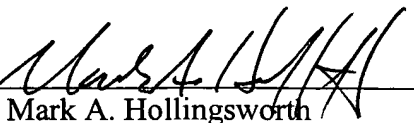
No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that a reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Forms 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

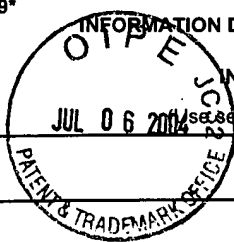
Respectfully submitted,

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Dated: June 30, 2004

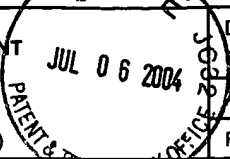
By: 
Mark A. Hollingsworth
Reg. No. 38,491

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|--|------------------------------|-----------------------------------|
| FORM 1449* INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (attach several sheets if necessary) | Docket Number: GUID.628PA | Application Number: 10/804,476 |
| | Applicant: WAGNER et al. | |
| | Filing Date: 3/19/2004 | Group Art Unit: 3762 |



| U.S. PATENT DOCUMENTS | | | | | | |
|-----------------------|--------------|----------|------------------|-------|----------|-------------------------------|
| EXAMINER INITIAL | DOCUMENT NO. | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
| | 6,622,046 | 09/16/03 | Fraley et al. | | | |
| | 6,615,083 | 09/02/03 | Kupper | | | |
| | 6,607,509 | 08/19/03 | Bobroff et al. | | | |
| | 6,564,106 | 05/13/03 | Guck et al. | | | |
| | 6,522,915 | 02/18/03 | Ceballos et al. | | | |
| | 6,512,940 | 01/28/03 | Brabec et al. | | | |
| | 6,487,443 | 11/26/02 | Olson et al. | | | |
| | 6,440,066 | 08/27/02 | Bardy | | | |
| | 6,438,410 | 08/20/02 | Hsu et al. | | | |
| | 6,398,728 | 06/04/02 | Bardy | | | |
| | 6,368,284 | 04/09/02 | Bardy | | | |
| | 6,358,203 | 03/19/02 | Bardy | | | |
| | 6,336,903 | 01/08/02 | Bardy | | | |
| | 6,312,378 | 11/06/01 | Bardy | | | |
| | 6,280,462 | 08/28/01 | Hauser et al. | | | |
| | 6,280,380 | 08/28/01 | Bardy | | | |
| | 6,277,072 | 08/21/01 | Bardy | | | |
| | 6,270,457 | 08/07/01 | Bardy | | | |
| | 6,259,947 | 07/10/01 | Olson et al. | | | |
| | 6,221,011 | 04/24/01 | Bardy | | | |
| | 6,148,230 | 11/14/00 | KenKnight | | | |
| | 6,141,581 | 10/31/00 | Olson et al. | | | |
| | 6,055,454 | 04/25/00 | Heemels | | | |
| | 6,044,298 | 03/28/00 | Salo et al. | | | |
| | 5,957,956 | 09/28/99 | Kroll et al. | | | |
| | 5,916,243 | 06/29/99 | KenKnight et al. | | | |
| | 5,895,414 | 04/20/99 | Sanchez-Zambrano | | | |
| | 5,855,593 | 01/05/99 | Olson et al. | | | |
| | 5,836,987 | 11/17/98 | Baumann et al. | | | |
| | 5,827,326 | 10/27/98 | Kroll et al. | | | |

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|---|-----------------|
| EXAMINER | DATE CONSIDERED |
| EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant. | |

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|------------|--|--|------------------------------|-----------------------------------|
| FORM 1449* | INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary) |  | Docket Number: GUID.628PA | Application Number: 10/804,476 |
| | | | Applicant: WAGNER et al. | Group Art Unit: 3762 |
| | | | Filing Date: 3/19/2004 | |

| | | | | | | |
|--|-----------|----------|------------------|--|--|--|
| | 5,724,984 | 03/10/98 | Arnold et al. | | | |
| | 5,704,365 | 01/06/98 | Albrecht et al. | | | |
| | 5,697,953 | 12/16/97 | Kroll et al. | | | |
| | 5,683,431 | 11/04/97 | Wang | | | |
| | 5,662,688 | 09/02/97 | Haefner et al. | | | |
| | 5,641,326 | 06/24/97 | Adams | | | |
| | 5,634,938 | 06/03/97 | Swanson et al. | | | |
| | 5,620,466 | 04/15/97 | Haefner et al. | | | |
| | 5,603,732 | 02/18/97 | Dahl et al. | | | |
| | 5,545,202 | 08/13/96 | Dahl et al. | | | |
| | 5,545,186 | 08/13/96 | Olson et al. | | | |
| | 5,540,727 | 07/30/96 | Tockman et al. | | | |
| | 5,531,779 | 07/02/96 | Dahl et al. | | | |
| | 5,468,254 | 11/21/95 | Hahn et al. | | | |
| | 5,441,518 | 08/15/95 | Adams et al. | | | |
| | 5,439,482 | 08/08/95 | Adams et al. | | | |
| | 5,411,539 | 05/02/95 | Neisz | | | |
| | 5,411,525 | 05/02/95 | Swanson et al. | | | |
| | 5,411,031 | 05/02/95 | Yomtov | | | |
| | 5,397,342 | 03/14/95 | Heil, Jr. et al. | | | |
| | 5,391,200 | 02/21/95 | KenKnight et al. | | | |
| | 5,388,578 | 02/14/95 | Yomtov et al. | | | |
| | 5,376,106 | 12/27/94 | Stahmann et al. | | | |
| | 5,372,606 | 12/13/94 | Lang et al. | | | |
| | 5,366,496 | 11/22/94 | Dahl et al. | | | |
| | 5,360,442 | 11/01/94 | Dahl et al. | | | |
| | 5,331,966 | 07/26/94 | Bennett et al. | | | |
| | 5,318,597 | 06/07/94 | Hauck et al. | | | |
| | 5,314,459 | 05/24/94 | Swanson et al. | | | |
| | 5,314,430 | 05/24/94 | Bardy | | | |
| | 5,313,953 | 05/24/94 | Yomtov et al. | | | |
| | 5,301,677 | 04/12/94 | Hsung | | | |

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|---|-----------------|
| EXAMINER | DATE CONSIDERED |
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FORM 1449*

INFORMATION DISCLOSURE STATEMENT

IN AN APPLICATION

(Use several sheets if necessary)

Docket Number:
GUID.628PAApplication Number:
10/804,476

Applicant: WAGNER et al.

Filing Date: 3/19/2004

Group Art Unit: 3762

| | | | | | | |
|--|--------------|------------|---------------------|--|--|--|
| | 5,300,106 | 04/05/94 | Dahl et al. | | | |
| | 5,292,338 | 03/08/94 | Bardy | | | |
| | 5,284,136 | 02/08/94 | Hauck et al. | | | |
| | 5,261,400 | 11/16/93 | Bardy | | | |
| | 5,230,337 | 07/27/93 | Dahl et al. | | | |
| | 5,209,229 | 05/11/93 | Gilli | | | |
| | 5,203,348 | 04/20/93 | Dahl et al. | | | |
| | 5,179,945 | 01/19/93 | Van Hofwegen et al. | | | |
| | 5,170,784 | 12/15/92 | Ramon et al. | | | |
| | 5,133,353 | 07/28/92 | Hauser | | | |
| | 5,036,849 | 08/06/91 | Hauck et al. | | | |
| | 4,953,551 | 09/04/90 | Mehra et al. | | | |
| | 4,562,841 | 01/07/86 | Brockway et al. | | | |
| | 6,480,733 B1 | 11/12/2002 | Turcott | | | |
| | 6,415,174 B1 | 07/2/2002 | Bebhani et al. | | | |
| | 6,409,675 B1 | 06/25/2002 | Turcott | | | |
| | 6,491,639 B1 | 12/10/2002 | Turcott | | | |
| | 2003/0212436 | 11/13/03 | Brown | | | |
| | 2003/0097153 | 05/22/03 | Bardy et al. | | | |
| | 2003/0088286 | 05/08/03 | Ostroff et al. | | | |
| | 2003/0088283 | 05/08/03 | Ostroff | | | |
| | 2003/0088282 | 05/08/03 | Ostroff | | | |
| | 2003/0088281 | 05/08/03 | Ostroff et al. | | | |
| | 2003/0088280 | 05/08/03 | Ostroff | | | |
| | 2003/0088279 | 05/08/03 | Rissmann et al. | | | |
| | 2003/0088278 | 05/08/03 | Bardy et al. | | | |
| | 2003/0069609 | 04/10/03 | Thompson | | | |
| | 2003/0045904 | 03/06/03 | Bardy et al. | | | |
| | 2003/0036778 | 02/20/03 | Ostroff et al. | | | |
| | 2003/0023175 | 01/30/03 | Arzbaeher et al. | | | |
| | 2003/0004552 | 01/02/03 | Plombon et al. | | | |
| | 2003/0004546 | 01/02/03 | Casey | | | |

EXAMINER

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FQRM 1449*

INFORMATION DISCLOSURE STATEMENT

IN AN APPLICATION

(Use several sheets if necessary)

Docket Number:
GUID.628PAApplication Number:
10/804,476Applicant: WAGNER *et al.*

Filing Date: 3/19/2004

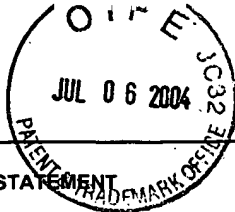
Group Art Unit: 3762

| | | | | | | |
|--|--------------|----------|-----------------|--|--|--|
| | 2002/0120299 | 08/29/02 | Ostroff et al. | | | |
| | 2002/0107559 | 08/08/02 | Sanders et al. | | | |
| | 2002/0107549 | 08/08/02 | Bardy et al. | | | |
| | 2002/0107548 | 08/08/02 | Bardy et al. | | | |
| | 2002/0107547 | 08/08/02 | Erlinger et al. | | | |
| | 2002/0107546 | 08/08/02 | Ostroff et al. | | | |
| | 2002/0107545 | 08/08/02 | Rissmann et al. | | | |
| | 2002/0107544 | 08/08/02 | Ostroff et al. | | | |
| | 2002/0103510 | 08/01/02 | Bardy et al. | | | |
| | 2002/0095184 | 07/18/02 | Bardy et al. | | | |
| | 2002/0091414 | 07/11/02 | Bardy et al. | | | |
| | 2002/0082658 | 06/27/02 | Heinrich et al. | | | |
| | 2002/0072773 | 06/13/02 | Bardy et al. | | | |
| | 2002/0068958 | 06/06/02 | Bardy et al. | | | |
| | 2002/0052636 | 05/02/02 | Bardy et al. | | | |
| | 2002/0049476 | 04/25/02 | Bardy et al. | | | |
| | 2002/0049475 | 04/25/02 | Bardy et al. | | | |
| | 2002/0042634 | 04/11/02 | Bardy et al. | | | |
| | 2002/0042630 | 04/11/02 | Bardy et al. | | | |
| | 2002/0042629 | 04/11/02 | Bardy et al. | | | |
| | 2002/0035381 | 03/21/02 | Bardy et al. | | | |
| | 2002/0035380 | 03/21/02 | Rissmann et al. | | | |
| | 2002/0035379 | 03/21/02 | Bardy et al. | | | |
| | 2002/0035378 | 03/21/02 | Bardy et al. | | | |
| | 2002/0035377 | 03/21/02 | Bardy et al. | | | |
| | 2002/0035376 | 03/21/02 | Bardy et al. | | | |

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| | Applicant: WAGNER <i>et al.</i> | |
| | Filing Date: 3/19/2004 | Group Art Unit: 3762 |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--|--------------|---|---------|-------|----------|-------------|
| | DOCUMENT NO. | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION |
| | WO 92/20402 | 26 Nov. 1992 | WO | | | YES |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | | |
| | | Renee Hartz <i>et al.</i> , <i>New Approach to Defibrillator Insertion</i> , J. Thoracic Cardiovascular Surgery, Vol. 97, pp. 920-922 (1989). | | | | |
| | | Theofilos M. Kolettis, MD, PhD <i>et al.</i> , <i>Submammary Implantation of a Cardioverter-Defibrillator with a Nonthoractomy Lead System</i> , Am. Heart J., Vol. 126, pp. 1222-1223 (Nov. 1993) | | | | |
| | | John C. Schuder <i>et al.</i> , <i>Transthoracic Ventricular Defibrillation in the Dog with Truncated and Untruncated Exponential Stimuli</i> , IEEE Trans. On Bio-Medical Engin., Vol. BME-18, No. 6, pp. 410-415 (Nov. 1971). | | | | |
| | | John C. Schuder <i>et al.</i> , <i>Ventricular Defibrillation in the Dog Using Implanted and Partially Implanted Electrode Systems</i> , Am. J. of Cardiology, Vol. 33, pp. 243-247 (Feb. 1974). | | | | |
| | | John C. Schuder <i>et al.</i> , <i>Experimental Ventricular Defibrillation with an Automatic and Completely Implanted System</i> , Trans. Am. Soc. Artif. Int. Organs, Vol. 16, pp. 207-212 (1970). | | | | |
| | | Karel Smits & Marek Malik, <i>Defibrillation Threshold (DFT) Model of a Fully Subcutaneous ICD System</i> , Europace Supplements, Vol. 2, June 2001, page B83, column 778 (best copy available). | | | | |
| | | Stirbis <i>et al.</i> , <i>Optmizing the Shape of Implanted Artificial Pacemakers</i> , Kaunas Medical Institute. Translated from Meditsinskaya Tekhnika, No. 6, pp. 25-27 (1986). | | | | |
| | | Charles T. Leng <i>et al.</i> , <i>Lead Configuration for Defibrillator Implantation in a Patient with Congenital Heart Disease and a Mechanical Prosthetic Tricuspid Valve</i> , PACE, Vol. 24, No. 8, pp. 1291-1292 (Aug. 2001). | | | | |
| | | Park & Pollock, <i>Use of an Implantable Cardioverter Defibrillator in an Eight-Month-Old Infant with Ventricular Fibrillation Arising from a Myocardial Fibroma</i> , PACE, Vol. 22, No. 1, pp. 138-139 (Jan. 1999). | | | | |
| | | Rainer Gradaus M.D. <i>et al.</i> , <i>Nonthoracotomy Implantable Cardioverter Defibrillator Placement in Children: Use of a Subcutaneous Array Leads and Abdominally Placed Implantable Cardioverter Defibrillators in Children</i> , J. of Cardiovascular Electrophysiology, Vol. 12, No. 3, pp. 356-360 (March 2001) | | | | |

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|---|-----------------|
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